Complete Summary

GUIDELINE TITLE

Helicobacter pylori infection in children: recommendations for diagnosis and treatment.

BIBLIOGRAPHIC SOURCE(S)

Gold BD, Colletti RB, Abbott M, Czinn SJ, Elitsur Y, Hassall E, Macarthur C, Snyder J, Sherman PM. Helicobacter pylori infection in children: recommendations for diagnosis and treatment. J Pediatr Gastroenterol Nutr 2000 Nov;31(5):490-7. [64 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Helicobacter pylori infection
- Helicobacter pylori-related diseases

GUIDELINE CATEGORY

Diagnosis
Evaluation
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To assist primary care physicians, nurse practitioners, physician assistants, and pediatric gastroenterologists in the evaluation and treatment of suspected or diagnosed Helicobacter pylori-associated disease in children and adolescents

TARGET POPULATION

Children and adolescents with suspected or diagnosed:

- Helicobacter pylori infection
- Helicobacter pylori-related diseases

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Assessment

1. Invasive tests for Helicobacter pylori requiring endoscopy
    - Biopsies and histology
    - Rapid urease testing
    - Bacterial culture
    - Polymerase chain reaction of bacterial DNA
2. Non-invasive tests for H. pylori
    - Serum and whole blood tests for H. Pylori antibody (e.g. enzyme-linked immunosorbent assays [ELISAs]
    - Saliva test for H. pylori antibody
    - Urine test for H. pylori antibody
    - Stool test for H. pylori antigen
    - Urea breath testing

Treatment

Three or four medications given once or twice daily, for one to two weeks.

First-line options:

1. Amoxicillin + clarithromycin + proton pump inhibitor [PPI] (omeprazole or other PPI)
2. Amoxicillin + metronidazole + PPI
3. Clarithromycin + metronidazole + PPI

Second-line options:

1. Bismuth subsalicylate + metronidazole + PPI + an additional antibiotic (amoxicillin or tetracycline or clarithromycin)
2. Ranitidine bismuth-citrate + clarithromycin + metronidazole

Note: The optimum treatment regimen for eradicating H. pylori in children has not been determined.

MAJOR OUTCOMES CONSIDERED

- Detection of children and adolescents with Helicobacter pylori and Helicobacter pylori-related diseases who need treatment
- Sensitivity and specificity of diagnostic tests
- Rate of symptomatic relief
- Medication and treatment side effects
- Eradication of Helicobacter pylori in children and adolescents

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

To develop evidence-based guidelines, articles published in English from January 1966 through May 1999 on H. pylori in children were searched. Articles on diagnosis and treatment were sought separately. Letters, editorials, case reports, abstracts, and reviews were excluded. Evidence tables were prepared based on 16 articles on clinical presentation, 9 articles on diagnostic studies, and 30 articles on therapy. Subsequently, additional articles were identified and reviewed. When the pediatric literature was insufficient, the adult literature was also considered.

NUMBER OF SOURCE DOCUMENTS

55+

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Categories of the Quality of Evidence

I Evidence obtained from at least one properly designed randomized controlled study.

II-1 Evidence obtained from well-designed cohort or case-controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-controlled analytic studies, preferably from more than one center or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Evidence tables were prepared based on 16 articles on clinical presentation, 9 articles on diagnostic studies, and 30 articles on therapy. Subsequently, additional articles were identified and reviewed. When the pediatric literature was insufficient, the adult literature was also considered. Articles were evaluated using published criteria.

By using the methods of the Canadian Preventive Services Task Force, the quality of evidence of each of the recommendations made by the committee was determined and is summarized in Table 1 in the original guideline document.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Nominal Group Technique)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Committee based its recommendations on integration of the literature review with expert opinion. Consensus was achieved through Nominal Group Technique, a structured, quantitative method. Using the methods of the Canadian Preventive Services Task Force, the quality of evidence of each of the recommendations made by the Helicobacter pylori Infection Guideline Committee was determined and is summarized in Table 1 of the original guideline.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

All comments submitted by peer review were considered and where appropriate, modifications were made.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline recommendations. Refer to the full text for additional information, including detailed information on dosing, possible side effects, and other interventions.

Each recommendation is identified as falling into one of five categories of evidence, indicated by a bracketed Roman numeral. The five categories represent varying levels of clinical confidence regarding the recommendation.

Definitions for the categories of evidence (I, II-1, II-2, II-3, III) are provided at the end of the Major Recommendations field.

How reliable are tests for Helicobacter pylori (H. pylori) infection?

Currently, the diagnosis of H. pylori-mediated disease can be made reliably only through the use of endoscopy with biopsy. [II, III]

Presently available commercial serologic tests are frequently unreliable for screening children for the presence of H. pylori infection. [II]

Urea breath testing, although promising, has not been studied sufficiently in children. [II]

When is testing indicated?

It is recommended that testing be performed in children with endoscopically diagnosed, or radiographically definitive, duodenal or gastric ulcers. [I]

It is recommended that children with recurrent abdominal pain, in the absence of documented ulcer disease, not be tested for H. pylori infection. [II]

Testing for H. pylori infection is not recommended in asymptomatic children. [II]

Routine screening of children with a family history of gastric cancer or recurrent peptic ulcer disease is not recommended. [II]

Testing following treatment of documented H. pylori is recommended, especially with complicated peptic ulcer disease (i.e., bleeding, perforation, or obstruction). For patients who remain symptomatic after treatment, it is recommended that endoscopy and biopsy be performed to evaluate for the persistence of H. pylori-associated peptic ulcer disease. [I, II]

If pathological evidence of mucosa-associated lymphoid tissue (MALT) lymphoma is documented, then testing for H. pylori is recommended. [II]

When is treatment of H. pylori infection indicated?

Eradication treatment is recommended for children who have a duodenal ulcer or gastric ulcer identified at endoscopy and H. pylori detected on histology. [I]

A prior history of documented duodenal or gastric ulcer disease is an indication for treatment if active H. pylori infection is documented. [I]

There is no compelling evidence for treating children with H. pylori infection and non-ulcer dyspepsia or functional recurrent abdominal pain. [III]

Treatment is not recommended for H. pylori-infected children residing in chronic care facilities; children with unexplained short stature; or children at increased risk for acquisition of infection, including asymptomatic children who have a family member with either peptic ulcer disease or gastric cancer. [III]

What is the preferred treatment of H. pylori infection in children?

It is recommended that treatment consist of three of four medications, given once or twice daily, for one to two weeks (see Table 3 in the original guideline for recommended eradication therapies). [I]

Definitions:

Categories of the Quality of Evidence

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see Major Recommendations)

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate and cost-effective diagnosis and treatment of Helicobacter pylori and Helicobacter pylori-related disease in children and adolescents
- Eradication of Helicobacter pylori in children and adolescents

POTENTIAL HARMS

Risks associated with treatment of Helicobacter pylori in children and adolescents include:

- Complications connected with diagnostic gastrointestinal endoscopy, which is an invasive procedure requiring sedation and anesthesia
- Complications associated with antibiotic treatment, such as adverse drug reactions and the development of antibiotic resistance

QUALIFYING STATEMENTS

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- This guideline may not be directly relevant to children living in communities where there is a higher frequency of gastric colonization by Helicobacter pylori.
- The recommendations are a general guideline and are not intended as a substitute for clinical judgment or as a protocol for the management of all patients with this problem.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Nov

GUIDELINE DEVELOPER(S)

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition - Professional Association

SOURCE(S) OF FUNDING

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition

GUIDELINE COMMITTEE

Helicobacter pylori Infection Guideline Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Benjamin D. Gold; Richard B. Colletti; Myles Abbott; Steven J. Czinn; Yoram Elitsur; Eric Hassall; Colin Macarthur; John Snyder; Philip M. Sherman

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from NASPGHAN, PO Box 6, Flourtown, PA 19031; Telephone (215) 233-0808; Fax (215) 233-3939; E-mail: naspghan@naspghan.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on June 9, 2003. The information was verified by the guideline developer on June 16, 2003.

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